

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D2122615	<b>(X3) Date Survey Completed</b>  03/30/2018
<b>Name of Provider or Supplier</b>  Beacon Biomedical Inc	<b>Street Address, City, State</b>  275 N Gateway Dr Ste 145, Phoenix, AZ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5423</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of established performance specification documentation for the Elisa Laboratory Developed Test (LDT), BeScreened-CRC, used to test patient blood specimens and interview with the facility personnel, the laboratory failed to demonstrate the effects of the patients' clinical conditions, disease states, and medications as interfering substances that may effect the analytical specificity of the test system. Findings include. 1. During the survey conducted on March 30, 2018, the laboratory presented documentation that demonstrated the effects that matrix components may have on the test system as interfering substances which may limit the ability to detect, identify or quantitate a targeted analyte, but there was no documentation indicating if the patients' clinical conditions, disease states, and any common medications may effect and/or inhibit the analytical specificity of the test system. 2. The facility personnel acknowledged that there was no specific analysis performed that included the effects of the patients' clinical conditions, disease states and common medications as possible interfering substances that may effect analytical specificity of the test system. 3. The laboratory started patient testing using the LDT,</p>

BeScreened-CRC, in January 2018 and tested approximately 10 patient samples since testing began.